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BCF S.E.N.C.R.L. / LLP

PCT

**WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Date of mailing
 (date/month/year)

02 March 2005 (02-03-2005)

Applicant's or agent's file reference
 08831-007

FOR FURTHER ACTION
 See paragraph 2 below

International application no
PCT/CA2004/001851

International filing date (date/month/year)
 21 October 2004 (21-10-2004)

Priority date (date/month/year)
 23 October 2003 (23-10-2003)

International Patent Classification (IPC) or both national classification and IPC

IPC⁷ A61M 16/00, A61H 31/02

Applicant **MAQUET CRITICAL CARE AB ET AL**

1. This opinion contains indications relating to the following items :

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA
 Commissioner of Patents
 Canadian Patent Office
 Box PCT, Ottawa/Gatineau K1A 0C9

Facsimile No. (819) 953-9538

Authorized officer

Eric Lafontaine (819) 956-9965.

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language which it was filed, unless otherwise indicated under this item.

- ☐ This opinion has been established on the basis of a translation from the original language into the following language __, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III
applicability

Non-establishment of opinion with regard to novelty, inventive step and industrial

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of :

☐ the entire international application

☒ claims Nos. 1-22

because

☒ the said international application, or the said claims Nos. 1-22 relate to the following subject matter which does not require an international preliminary examination (*specify*) :

The present application relates to a method and system for delivering combined positive and negative pressure assist ventilation to a patient.

The aforementioned claims relate to a method for delivering combined positive and negative pressure assist ventilation to a patient by applying a positive pressure to the patient's airways and applying a negative pressure around the patient's ribcage or abdomen.

Moreover, for the assessment of present claims 1-22 under Rule 43bis.1(a)(i) and Article 34(4)(a)(i) PCT whether they are industrially applicable, no unified criteria exists in the PCT.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. ____ are so unclear that no meaningful opinion could be formed (*specify*) :

☐ the claims, or said claims Nos. ____ are so inadequately supported by the description that no meaningful opinion

☐ no international search report has been established for said claims Nos. ____.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that :

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

Box No. V reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-50	YES
	Claims	none	NO
Inventive step (IS)	Claims	11, 13, 17, 20-22, 27, 39, 41, 45, 48-50	YES
	Claims	1-10, 12, 14-16, 18, 19, 23-26, 28-38, 40, 42-44, 46, 47	NO
Industrial applicability (IA)	Claims	23-50	YES
	Claims		NO

2. Citations and explanations :

Reference is made to the following documents:

D1 = US 5 749 830
D2 = WO 99/43374
D3 = WO 01/08735
D4 = US 5 871 008

I. Novelty:

1. The combination of features disclosed in claims 1 to 50 are considered to be novel as no reference disclosed all the elements and limitations of the claimed device and methods. The subject matter of claims 1 to 50 therefore complies with PCT Article 33(2).

II. Inventive Step:

2. Document D1 discloses a resuscitator, respirator and/or incubator comprising a head chamber and a body chamber for providing positive and negative pressures (column 4, line 39 to column 5, line 59) as recited in independent claims 1, 23 and 30. Furthermore, Document D1 discloses means for controlling the operation of the positive and negative ventilators (column 5, line 60 to column 6, line 29). Document D1 does not specifically disclose applying only negative pressure to the patient's ribcage or abdomen or providing only positive pressure to the airways. A person skilled in the art would have been able to modify these elements to work purely with positive pressure for the airways and negative pressure for the ribcage, therefore, these elements do not involve an inventive step.

2.2 Dependent claims 2, 3, 12, 24, 31, 32 and 40, further recite:

- applying the positive pressure to the airways and the negative pressure to the ribcage simultaneously
- means for adjusting the levels of pressure to minimize hemodynamic adverse effects
- means for synchronizing triggering and termination of the applied pressures, all recited in D1 column 4, line 39 to column 6, line 29.

As such, the subject matter of claims 1 to 3, 12, 23, 24, 30 to 32 and 40 is not deemed to fulfill the requirements of PCT Article 33(3), in view of document D1.

3. Document D2 discloses a device responsive to myoelectrical activity of the diaphragm for triggering ventilatory support (page 4, line 8 to page 8, line 17, page 11, lines 24 to 27). Therefore, the added features of claims 4, 5, 25, 28, 33 and 34 of providing a sensor of neural inspiratory activation and a controller responsive to this detection do not involve any inventive step. As such, the subject matter of claims 4, 5, 25, 28, 33 and 34 is not deemed to fulfill the requirements of PCT Article 33(3), in view of document D1 and D2.

4. Document D3 discloses a target drive ventilation gain controller (page 4, line 6 to page 7, line 25). Therefore, the added features of claims 6 to 10, 26 and 35 to 38 of supplying a target level of neural inspiratory activation of the patient, a sensor of neural inspiratory activation and a means for controlling the pressure do not involve any inventive step. As such, the subject matter of claims 6 to 10, 26 and 35 to 38 is not deemed to fulfill the requirements of PCT Article 33(3), in view of document D1 and D3.

(Continued in Supplemental Box)

Box No. VIII

Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

The incorporations by reference on page 6, line 13 and page 13, line 25 do not comply with Article 5 of the PCT, because the description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art without referring to other documents.

The inclusion of "and/or" (claims 1, 2, 11 to 17, 23, 24, 27, 30, 31, 39 and 41 to 45) causes ambiguity (PCT Article 6).

Claims 4, 6, 11 to 14, 21, 22 and 49 are indefinite and do not comply with PCT Article 6. The double inclusion of any element renders the claims unclear. The terms: "a positive pressure" (claims 4 and 6, line 2), "a negative pressure" (claims 11 to 14 and 21, line 2), "an intrathoracic pressure estimate" (claim 22, line 3) and "a patient's airway" (claim 49, line 4) have been defined previously in the claims. The aforementioned terms should therefore be referred to using a definite article.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V:

5. Document D4 discloses a miniature high-frequency ventilator which determines a required pressure swing and further applies negative end-expiratory pressure to the chamber (column 4, lines 18 to 35, column 13, line 10 to column 14, line 15, column 15, line 65 to column 16, line 31 and figures 1 to 3 and 27 to 29). Therefore, the added features of claims 14 to 16, 18, 19, 29, 42 to 44, 46 and 47 of providing a sensor of abdominal pressure swing and a controller responsive to this determined pressure swing to control the negative pressure and the further added feature of providing negative end-expiratory pressure over the abdomen while providing inspiratory negative pressure assist ventilation do not involve any inventive step. As such, the subject matter of claims 14 to 16, 18, 19, 29, 42 to 44, 46 and 47 is not deemed to fulfill the requirements of PCT Article 33(3), in view of document D1 and D4.

6. The combination of features disclosed in dependent claims 11, 13, 17, 20 to 22, 27, 39, 41, 45 and 48 to 50 is not disclosed in the available prior art and involves an inventive step over the available prior art.

III. Industrial applicability

The claimed subject matter of claims 23 to 50 is considered to be industrially applicable and thus fulfilling the requirements of PCT Article 33(4).

For the assessment of present claims 1 to 22 under Rule 43bis.1(a)(i) and Article 34(4)(a)(i) PCT whether they are industrially applicable, no unified criteria exists in the PCT.